

0811 5 OCT 28 A8:58

October 26, 2005

Division of Docket's Management
Food and Drug Administration (HFD-350)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION (ADDENDUM)

Dear Sir or Madam:

The undersigned submits this addendum to our previously submitted Citizen Petition of October 21, 2005 (attached here for reference) under 21 CFR 10.30 or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs, including under 21 CFR 5.10.

The addendum contains four copies each of the following publications which were cited in the October 21, 2005 Citizen Petition but for which only abstracts were previously available.

- Ehrenreich H, Poser W. Dependence on tramadol. Clin Investig 1993;72:76.
- Murano T, Yamamoto H, Endo N et al. Studies on dependence on tramadol in rats. Arzneimittel-Forschung-Drug Research 1978;28: 152-158.
- Yanagita T. Drug dependence potential of 1-(m-Methoxyphenyl)-2-(dimethyl aminomethyl)-cyclohexan-1-ol Hydrochloride (Tramadol) tested in monkeys. Arzneimittel-Forschung-Drug Research 1978;28:158-63.
- Rodriguez Villamanan JC, Albaladejo Blanco C, Sanchez Sanchez A, Carvajal A, Martin Arias L, Carcia del Pozo, J. Withdrawal syndrome after long-term treatment with tramadol. Br J Gen Pract 2000;50:406.
- Reeves RR, Liberto V. Abuse of combinations of carisoprodol and tramadol. South Med J. 2001;94:512-4.

A. Action Requested

The Petitioner requests that the attached publications be appended to the original Citizen Petition dated October 21, 2005.

B. Statement of Grounds

The original Citizen Petition contained the required citations. However, the above five full publications were unavailable on October 21, 2005.

C. Environmental Impact

The action requested by the Petitioner is exempt from the requirements for an

2005P-0429

SUP 1

Environmental impact Statement or an Environmental Assessment under 21 CFR 25.31.

D. Economic Impact

The Petitioner does not believe that an economic impact statement is applicable, but will agree to provide such an analysis if requested by the Commissioner in accordance with 21 CFR 10.30(b).

E. Certification

The undersigned certifies that to the best knowledge of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

A handwritten signature in black ink, appearing to read 'Najib Babul', with a stylized flourish at the end.

Najib Babul, PharmD
CEO

Attachment: References